

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

12 Sep 2026

### Association of response to doxycycline and Azithromycin antibiotics therapy with Angiotensin converting enzyme polymorphism in patients with moderate acne vulgaris

#### Protocol summary

##### Study aim

Determining the relationship between response to doxycycline and azithromycin antibiotic treatment with angiotensin-converting enzyme (ACE) gene polymorphism in patients with moderate acne vulgaris referred to Gonabad skin clinics in 2023

##### Design

Patients with moderate acne will be divided into two groups of 27 people, one group will receive doxycycline 100 mg daily along with topical treatment (benzoyl peroxide and tretinoin) and the other group will receive azithromycin 250 mg every other day along with topical treatment (benzoyl peroxide and tretinoin). Clinical trial without control group, with parallel groups, without blind strain, block randomization, and data will be analyzed after collection with statistical software SPSS version 22.

##### Settings and conduct

After obtaining consent from the patients and dividing them into two groups, one group will receive doxycycline and the other group will receive azithromycin, and then we will investigate the polymorphism.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Acne vulgaris with moderate severity according to the MAS SCORE classification system 2. Suffering from acne vulgaris with moderate severity according to Weishampain's classification system 3. Age over 12 years

##### Intervention groups

one group will receive doxycycline 100 mg daily along with topical treatment (benzoyl peroxide and tretinoin) and the other group will receive azithromycin 250 mg every other day along with topical treatment (benzoyl peroxide and tretinoin).

##### Main outcome variables

angiotensin converting enzyme gene polymorphism; Age; gender; treatment; rate of response to treatment; recovery from the doctor's point of view; the level of

patient satisfaction; duration of acne; Family history of acne

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230305057628N1**

Registration date: **2023-03-14, 1401/12/23**

Registration timing: **registered\_while\_recruiting**

Last update: **2023-03-14, 1401/12/23**

Update count: **0**

##### Registration date

2023-03-14, 1401/12/23

##### Registrant information

##### Name

alireza tavakolizadeh

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 5725 7039

##### Email address

alirezatavakolizadeh@gmail.com

##### Recruitment status

##### Recruitment complete

##### Funding source

##### Expected recruitment start date

2023-03-11, 1401/12/20

##### Expected recruitment end date

2023-06-22, 1402/04/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
Association of response to doxycycline and Azithromycin antibiotics therapy with Angiotensin converting enzyme polymorphism in patients with moderate acne vulgaris

**Public title**  
Association of response to doxycycline and Azithromycin antibiotics therapy with Angiotensin converting enzyme polymorphism in patients with moderate acne vulgaris

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
 Acne vulgaris with moderate severity according to the MAS SCORE classification system  
 Suffering from acne vulgaris with moderate severity according to Weishampain's classification system  
**Exclusion criteria:**

**Age**  
From 12 years old

**Gender**  
Both

**Phase**  
2

**Groups that have been masked**  
No information

**Sample size**  
Target sample size: 54

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Permuted block randomization, At first, the people who meet the criteria for entering the study will be selected based on the purpose after obtaining the consent to participate in the study, and then the people will be divided into two intervention groups in the form of block allocation.

**Blinding (investigator's opinion)**  
Not blinded

**Blinding description**

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

ethics committee of gonabad university of medical sciences

#### Street address

House number 30, Imam Ali 2 street, gonabad city

#### City

gonabad

#### Province

Razavi Khorasan

#### Postal code

9691998984

#### Approval date

2023-02-26, 1401/12/07

#### Ethics committee reference number

IR.GMU.REC.1401.182

## Health conditions studied

### 1

#### Description of health condition studied

Acne vulgaris

#### ICD-10 code

L70.0

#### ICD-10 code description

Acne vulgaris

## Primary outcomes

### 1

#### Description

Angiotensin converting enzyme gene polymorphism

#### Timepoint

After the end of the treatment period

#### Method of measurement

PCR and electrophoresis

### 2

#### Description

Response to treatment

#### Timepoint

Before starting the treatment, after the end of the treatment

#### Method of measurement

MAS score

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: At first, the patients are examined by a dermatologist and the severity of their acne is measured based on the Michelson acne score, and the patients are subjected to standard Photography. Next, the patients are divided into two groups. The first group receives doxycycline 100 mg daily along with topical treatment (benzoyl peroxide and tretinoin).

#### Category

Treatment - Drugs

2

#### Description

Intervention group: At first, the patients are examined by a dermatologist and the severity of their acne is measured based on the Michelson acne score, and the patients are subjected to standard Photography. Next, the patients are divided into two groups. The second group receives 250 mg of azithromycin every other day along with topical treatment (benzoyl peroxide and tretinoin).

#### Category

Treatment - Drugs

### Recruitment centers

1

#### Recruitment center

##### Name of recruitment center

Bohloul hospital

##### Full name of responsible person

Hamideh mohammadzadeh

##### Street address

Bohloul hospital, Parastar Blvd, Gonabad city

##### City

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##### Province

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##### Postal code

9691797852

##### Phone

+98 51 5723 6832

##### Email

Mohammadzadeh.hamideh@yahoo.com

### Sponsors / Funding sources

1

#### Sponsor

##### Name of organization / entity

Gonabad University of Medical Sciences

##### Full name of responsible person

Leila sadegh moghadam

##### Street address

Gonabad University of Medical Sciences, Dr mehdizadeh Blvd, Gonabad city

##### City

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Mohammadzadeh.hamideh@yahoo.com

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Gonabad University of Medical Sciences

#### Proportion provided by this source

100

#### Public or private sector

Public

#### Domestic or foreign origin

Domestic

#### Category of foreign source of funding

empty

#### Country of origin

#### Type of organization providing the funding

Academic

### Person responsible for general inquiries

#### Contact

##### Name of organization / entity

Gonabad University of Medical Sciences

##### Full name of responsible person

hamide mohammadzadeh

##### Position

Assistant Professor

##### Latest degree

Specialist

##### Other areas of specialty/work

Dermatology

##### Street address

Bohloul hospital, Parastar Blvd, Gonabad city

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### Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Gonabad University of Medical Sciences

##### Full name of responsible person

hamide mohammadzadeh

##### Position

Assistant Professor

##### Latest degree

Specialist

##### Other areas of specialty/work

Dermatology

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

Gonabad University of Medical Sciences

**Full name of responsible person**

Hamideh mahammas

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dermatology

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Bohloul hospital, Parastar Blvd, Gonabad city

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**Province**

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**Postal code**

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**Phone**

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**Email**

Mohammadzadeh.hamideh@yahoo.com

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

All the data will be provided to the researchers without names and specifications.

**When the data will become available and for how long**

After completing the research project and publishing the article

**To whom data/document is available**

All researchers

**Under which criteria data/document could be used**

To conduct similar research, researchers can access the results of the project by referring to the research assistant of Gonabad University of Medical Sciences with a written consent letter from the research assistant.

**From where data/document is obtainable**

Research assistant of Gonabad University

**What processes are involved for a request to access data/document**

Researchers can have access to the results of the project by referring to the vice president of research of Gonabad University of Medical Sciences with a written consent letter from the vice president of research.

**Comments**